

VIA FEDERAL EXPRESS

Food and Drug Administration 555 Winderley Pl., Ste. 200 Maitland, Fl 32751

Ref: Entry No. Q98-0005760-9

Product: Fresh Asparagus (533 Cases/2,665 Kilograms)

WARNING LETTER

FLA-02-11

October 24, 2001

Michael B. Warren Chief Operations Officer Central American Produce 1500 West Atlantic Boulevard Pompano Beach, Florida 33069-2800

Dear Mr. Warren:

The Food and Drug Administration (FDA), on August 16 and 29, 2001, requested the location of this shipment of fresh asparagus for FDA examination. Since FDA did not receive a response, FDA called your firm on September 4, 2001, and requested that your firm determine the location of this entry. On September 10, 2001, FDA was notified by your firm that the product had already been distributed by mistake. The shipment was offered for import (imported) into the United States by your firm on August 2, 2001, under the above referenced entry number.

Not holding an entry intact pending a FDA release is a violation of Title 21, <u>Code of Federal Regulations</u> (21 CFR), Section 1.90. This section requires the importer to hold an imported article intact, pending a release notice from FDA. Failure to promptly correct this situation and prevent future premature distribution of imported products may result in requiring that future shipments be held in secured storage. Secured storage will be under the supervision and direction of U. S. Customs Service (Customs), such as in a bonded warehouse. You will be responsible for all costs incurred in secured storage.

We have requested that Customs order redelivery of the cases of fresh asparagus which were distributed without a FDA release. Failure to redeliver the missing product to Customs' custody may result in a penalty action at a later date.

We request a response in writing within fifteen (15) working days of receipt of this letter outlining the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent recurrence. In the event that the product is still available for examination, you should inform Customs and FDA if and when redelivery is accomplished.

Your written reply should be addressed to the Food and Drug Administration, Attention: Paul R. Bagdikian, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

Emma R. Singleton

Director, Florida District

Enclosure